

January 12, 2005

VIA FACSIMILE AND U.S. MAIL

Christine A. Sannerud, Ph.D.
Chief, Drug & Chemical Evaluation Section
Drug Enforcement Administration
600 Army-Navy Dr.
Rm. E6233
Arlington, VA 22202

Re: Request for Exception to Store Non-Controlled Substance in Secured Storage Area

Dear Dr. Sannerud:

Sepracor Inc. (Sepracor) respectfully requests a limited exception from the requirement in 21 C.F.R. 1301.72(b)(8)(ii) that registrants secure written permission the Special Agent in Charge of DEA for the ir area in order to store a non-controlled substance in their secured area for controlled substances. Sepracor seeks this exception pursuant to 21 C.F.R. 1307.03¹ for its product Lunesta[™] (eszopiclone) Tablets (Lunesta), which is not a controlled substance but which the Food and Drug Administration is recommending that DEA schedule as schedule IV.

This exception would ensure that any registrant receiving a stock of Lunesta will be able to provide the same security for Lunesta as would be provided for a controlled substance. Given FDA's conclusion that Lunesta should be scheduled, Sepracor believes that it would be appropriate for distributors of Lunesta to provide this level of security immediately.

Sepracor's distributor, Cord Logistics, has already requested written permission to store Lunesta in a secured controlled substance area, and Sepracor expects that other registrants receiving Lunesta will want to provide the same security. This form of security for Lunesta is appropriate and is consistent with 21 C.F.R. 1301.72(b)(8)(ii).² Because these registrants will be

¹ Section 1307.03 provides that "[a]ny person may apply for an exception to the application of any provision of this chapter by filing a written request stating the reasons for such exception."

² Section 1301.72(b)(8)(ii) provides as follows:

(ii) Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b), provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated. Any such permission tendered must be

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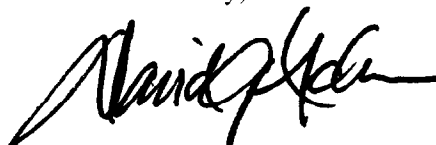
handling Lunesta in the same manner as a controlled substance, the use of the controlled substance area will not diminish security effectiveness of other controlled substances.

Although each registrant handling Lunesta could individually seek written permission from the Special Agent in Charge of their area, we believe it would be more efficient for DEA to grant a general exception from this requirement for Lunesta pursuant to 21 C.F.R. 1307.03, which could be communicated by Sepracor or its distributors to each registrant receiving Lunesta. This would reduce the administrative burden on DEA and would ensure that registrants receiving Lunesta will not have to hold the product in a less secure environment pending written permission from the respective Local Agents in Charge.

We have discussed this proposal in some detail with Charles Trant, Office of the Chief Counsel.

We would appreciate your expeditious handling of this request to ensure that registrants receiving Lunesta will have proper and immediate access to a secured area for storage of a product recommended for scheduling. If you have any questions, please feel free to call me at (202) 344-8014.

Sincerely,



David G. Adams
Counsel for Sepracor

cc: Charles Trant